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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

DI-5666 (112713-026)

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on _____

Signature _____

Typed or printed name _____

Application Number

09/990,673

Filed

November 13, 2001

First Named Inventor

Karoer et al.

Art Unit

3763

Examiner

Laura A. Bouchelle

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record. 48,769
Registration number _____

☐ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____



Signature

Ted J. Barthel

Typed or printed name

312 578-6846

Telephone number

October 6, 2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Karoor et al.
Appl. No.: 09/990,673
Conf. No.: 2485
Filed: November 13, 2001
Title: METHOD AND COMPOSITION FOR REMOVING UREMIC TOXINS IN
DIALYSIS PROCESSES
Art Unit: 3763
Examiner: Laura A. Bouchelle
Docket No.: DI-5666 (112713-026)

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

In response to the Advisory Action dated September 15, 2006 and in further response to the final Office Action dated June 7, 2006, please amend the above-identified patent application as follows:

Form PTO/SB/33, Pre-Appeal Brief Request for Review; and

Form PTO/SB/31, Notice of Appeal.

Remarks begin on page 2 of this paper.

REMARKS

This Paper, the Pre-Appeal Brief Request for Review, the Notice of Appeal, and the Petition for a one month extension of time are submitted in response to the Advisory Action mailed September 15, 2006 and in further response to the final Office Action mailed on June 7, 2006 having a shortened statutory response period that ended on September 7, 2006. This Paper is submitted within one month of the statutory response period end date, namely October 7, 2006. The Commissioner is hereby authorized to charge the amount of \$500.00 for the Notice of Appeal and the \$120.00 one month extension of time fee and any additional fees associated with this submission to Deposit Account number 02-1818.

Claims 1-11 and 59-63 are pending in this application. Claims 62-63 contain allowable subject matter. Claims 12-58 are withdrawn from consideration.

It is noted that Applicants' good faith effort to place the application in a condition for allowance was not entered by the Examiner. In response to the final Office Action, Applicant canceled claims 12-58 and amended claim 59. The Applicant also re-wrote claims 62-63, which contain allowable subject matter, in independent form in accordance with the Examiner's request. The Examiner did not enter any of these amendments into the record.

Claims 1, 4, 5, 8, and 9 were rejected under 35 U.S.C. § 103(a) for allegedly being obvious over U.S. Patent No. 5,944,684 to Roberts et al. (*Roberts*), in view of U.S. Patent No. 4,610,794 to Henne et al. (*Henne*). Claims 2 and 3 were rejected under 35 U.S.C. § 103(a) for allegedly being obvious over U.S. Patent No. 3,669,880 to Marantz (*Marantz*) in view of *Henne*. Claim 6 was rejected under 35 U.S.C. § 103(a) for allegedly being obvious over *Roberts* in view of *Henne*, and in further view of U.S. Patent No. 6,627,164 to Wong (*Wong*). Claim 7 was rejected under 35 U.S.C. § 103(a) for allegedly being obvious over *Roberts* in view of *Henne* and in further view of U.S. Patent No. 4,659,744 to Matsui (*Matsui*). Claim 10 was rejected under 35 U.S.C. § 103(a) for allegedly being obvious over *Marantz* in view of *Henne*. Claim 11 was rejected under 35 U.S.C. § 103(a) for allegedly being obvious over *Roberts* in view of *Henne* and in further view of U.S. Patent No. 5,618,441 to Rosa et al. (*Rosa*). Claim 59 was rejected under 35 U.S.C. § 103(a) for allegedly being obvious over *Roberts* in view of U.S. Patent No. 5,618,710 to Navia (*Navia*). Claim 60 was rejected under 35 U.S.C. § 103(a) for allegedly being obvious over *Roberts* in view of *Navia*, in view of *Henne*. Claim 61 was rejected under 35 U.S.C. § 103(a) for allegedly being obvious over *Roberts* in view of *Navia* and in further view of U.S.

Patent No. 4,386,611 to Kantorski et al. (*Kantorski*). Applicants respectfully traverse and disagree with these alleged rejections for the reasons set forth below.

No combination of *Roberts*, *Henne*, *Marantz*, *Wong*, *Matsui*, *Rosa*, *Navia* and/or *Kantorski* discloses or suggests a dialysis device having a body with individual layers of zirconium phosphate (ZP), urease, zirconium oxide (ZO), and carbon, the layers so arranged that a fluid entering the device contacts the ZP layer before contacting either the urease layer or the ZO layer as recited in independent claim 1. *Roberts* and *Marantz* each individually teach away from a dialysis device wherein incoming fluid first contacts a ZP layer. *Roberts* discloses a dialysis purification system having sorbent layers in a well-defined functional order. From fluid inlet to fluid outlet, the *Roberts* device entails the following sorbent layer configuration: a urease layer, a ZP layer, a ZO layer, and an activated carbon layer. *Roberts*, col. 3 lines 43-54, col. 6 lines 14-24, col. 8 lines 30-35. This urease-ZP-ZO-carbon layer order is a functional requirement of *Roberts*. *Roberts* requires the urease layer to be first in order to convert urea present in the ultrafiltrate solution to ammonia. The ZP layer, located downstream of the urease layer, is then able to adsorb the ammonia from the ultrafiltrate fluid. *Roberts*, col. 6 lines 14-24. Indeed, *Roberts* is clear that the urease layer is the first layer: “[t]he purification system consists of a layer of urease **followed by** layers of zirconium phosphate, hydrated zirconium oxide, and activated carbon.” *Roberts*, col. 8 lines 30-35 (emphasis added). Consequently, the incoming ultrafiltrate fluid first contacts *Roberts*’ urease layer before contacting any other layer. *Roberts* thereby teaches away from the dialysis device wherein the incoming fluid contacts the ZP layer before contacting the urease layer as recited in the present claims. Teaching away is a *per se* demonstration of non-obviousness. *In re Dow Chemical Co.*, 837 F.2d 469 (Fed. Cir. 1988). Consequently, any combination of *Henne*, *Marantz*, *Wong*, *Matsui*, *Rosa*, *Navia* and/or *Kantorski* with *Roberts* is likewise non-obvious.

Marantz discloses a dialysate system wherein incoming fluid first contacts a urease layer followed by contact with a ZP layer. *Marantz*, col. 2 lines 14-29, *see in particular* FIG. 2 (zirconium phosphate layer 22 downstream of urease layer 25). The *Marantz* system is constructed so that fluid entering the system contacts the urease layer first and the ZP layer second. *Marantz* therefore teaches away from the subject matter of claim 1. Consequently, any combination of *Roberts*, *Henne*, *Wong*, *Matsui*, *Rosa*, *Navia* and/or *Kantorski* with *Marantz* is non-obvious as teaching away is a *per se* demonstration of obviousness as discussed above.

Henne fails to fulfill the deficiencies of *Roberts*. *Henne* discloses a dialysis membrane composed of cuprammonium cellulose. *Henne*, col. 2 lines 15-22. The membrane may include additional adsorbent layers such as carbon, ZO, and ZP. *Henne*, col. 12 lines 43-55. *Henne*, however, has no disclosure whatsoever regarding a urease layer. A reference cannot disclose or suggest that which it does not have. In this case, *Henne* wholly lacks any disclosure even remotely related to a urease layer. Without the slightest hint of a urease layer, *Henne* cannot suggest a distinct membrane-layer configuration that includes a specific position for the urease layer with respect to the other layers. This attempt to combine *Henne*, which completely lacks any disclosure regarding a urease layer, with *Roberts*, a reference that teaches away from the present claims, is clear evidence that the Examiner is using the Applicant's own disclosure as a template to piece together isolated portions of the prior art in order to deprecate Applicant's claims. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988); *In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992). Such a combination demonstrates hindsight reasoning and is improper as a matter of law.

Even assuming *arguendo* that *Henne* is arguably combinable with *Roberts* (which it is not), no motivation would exist to combine *Henne* with *Roberts* as such a combination would run contrary to the intended purpose of *Roberts*. *Henne* discloses a dialysis membrane composed of cuprammonium cellulose and may include additional adsorbent layers such as carbon, ZO, and ZP. *Henne*, col. 2 lines 15-22, col. 12 lines 43-55. *Henne*, however, has no disclosure whatsoever regarding a urease layer. *Roberts*, on the other hand, requires the ultrafiltrate fluid to contact the urease layer before the ultrafiltrate fluid contacts the ZP layer. The urease layer converts the urea to ammonia. The ammonia can then be adsorbed by the ZP layer. *Roberts*, col. 6 lines 14-24. The assertion that *Henne* would motivate the skilled artisan to rearrange *Roberts'* layers in any manner (*i.e.*, the ZP layer being first) runs contrary to the intended purpose of *Roberts*—namely, *Roberts'* requirement of urea conversion to ammonium carbonate by the urease layer in order to enable subsequent absorption of the ammonia by the ZP layer. Thus, even if *Roberts* and *Henne* were combinable, no motivation would exist to combine these references as such a combination would run contrary to the intended purpose of *Roberts*.

Any combination of *Wong*, *Matsui*, *Rosa*, *Navia*, and/or *Kantorski* with *Roberts* and/or *Marantz* is non-obvious as *Roberts* and *Marantz* each individually teach away from independent claims 1-59. Even if *Wong*, *Matsui*, *Rosa*, *Navia*, and/or *Kantorski* were combinable with

Roberts and/or *Marantz*, these references would fail to fulfill the deficiencies of *Roberts* or *Marantz* as *Wong*, *Matsui*, *Rosa Navia*, and *Kantorski* have no disclosure whatsoever related to a multiple layer dialysis device, let alone a dialysis device having the layer configuration as recited in the present claims.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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BY 

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Dated: October 6, 2006